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North Carolina

Medicaid Pharmacy

Newsletter

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In This Issue...

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1-800-688-6696 or 919-851-8888

Policy and Procedures for Prescribing Synagis for 2007–2008

For the upcoming RSV season, Synagis will not require prior approval (PA) for NC Medicaid recipients. However, the responsibility for appropriate usage of Synagis will be placed on prescribers and pharmacy providers. The clinical criteria utilized in this policy are consistent with currently published American Academy of Pediatrics Red Book guidelines (on the Web at http://aapredbook.aappublications.org/cgi/content/full/2006/1/3.107—subscription required, or in *Red Book: 2006 Report of the Committee on Infectious Diseases, 27th Edition)*. Please ensure that the person completing the Synagis for RSV Prophylaxis form has verified that the conditions exist and are accurate. If a patient does not fit the published criteria and you still wish to prescribe Synagis, you must submit your request to DMA on the Request for Medical Review for Synagis Outside of Criteria form.

NC Medicaid will begin coverage of Synagis on October 15, 2007. During the season, **no more than five (5) monthly doses of Synagis can be obtained by using the Synagis for RSV Prophylaxis form or the Request for Medical Review for Synagis Outside of Criteria form. The number of doses should be adjusted if an infant received the first dose prior to a hospital discharge.** Delays in getting a request processed can occur if the patient does not have a Medicaid identification number or if the form is not complete.

The Synagis for RSV Prophylaxis form must be signed by the prescriber and submitted to the pharmacy distributor of choice. The Request for Medical Review for Synagis Outside of Criteria form must be signed by the prescriber and faxed to DMA at 919-715-1255.

Please refer to the following guidelines when submitting a request on the **Synagis for RSV Prophylaxis form:**

- **For the following four diagnoses, DOB must be on or after 10/15/05:**

  Chronic Lung Disease of Prematurity (Bronchopulmonary Dysplasia)

  The infant has Chronic Lung Disease (bronchopulmonary dysplasia) and has necessitated treatment (supplemental oxygen, bronchodilator, diuretic, corticosteroid) in the six months before the start of the season.

  Hemodynamically Significant Congenital Heart Disease

  Infants less than 12 months of age who are most likely to benefit include those receiving medication to control CHF, moderate to severe pulmonary hypertension, and/or cyanotic heart disease.

  Infants NOT at increased risk from RSV who generally should NOT receive immunoprophylaxis include: hemodynamically insignificant heart disease such as secundum atrial/septal defect, small VSD, pulmonic stenosis, uncomplicated aortic stenosis, mild coarctation of the aorta, PDA, lesions adequately corrected by surgery unless the infant continues on medication for CHF, mild cardiomyopathy where the infant is not receiving medical therapy.

Cystic Fibrosis

The infant has Cystic Fibrosis and either requires chronic oxygen or has been diagnosed with nutritional failure.

Severe Congenital Immunodeficiency

Severe combined immunodeficiency disease or severe acquired immunodeficiency syndrome.

- **Infant is born at an EGA of:**

  ≤ 28 weeks and DOB is on or after 10/15/06
  29-32 weeks and DOB is on or after 4/15/07

- **If born between 32 weeks and 1 day and 35 weeks and 0 days gestation, must be less than 6 months of age (DOB on or after 4/15/07) at the start of the season and have two or more defined risk factors:**

  - School-age Siblings
  - Attends Day Care
  - Severe Neuromuscular Disease
  - Exposure to prolonged wood burning heaters which are the primary source of heat for the family. Tobacco smoke is NOT a risk factor because it can be controlled by the family.
  - Congenital abnormalities of the airways.

Please adhere to the following instructions when submitting a request on the **Request for Medical Review for Synagis Outside of Criteria form.** This form is used for patients who do not explicitly meet the guidelines but whose providers still wish to prescribe Synagis. Please fill out the requested information and fax to DMA at **919-715-1255**. PLEASE NOTE THAT THIS IS THE ONLY FORM THAT **PRESCRIBERS** SHOULD FAX TO DMA.

The Synagis for RSV Prophylaxis form and the Request for Medical Review for Synagis Outside of Criteria form are available on the DMA Web site at http://www.dhhs.state.nc.us/dma/prov.htm.

NC Medicaid will allow Synagis claims processing to begin on October 10, 2007 to allow sufficient time for pharmacies to provide Synagis by October 15, 2007. Payment of Synagis claims prior to October 10, 2007 and after March 31, 2008 will not be allowed. Pharmacy providers should always indicate an accurate days' supply when submitting claims to NC Medicaid. Claims for Synagis doses that include multiple vial strengths must be submitted as a single compound drug claim. Synagis doses that require multiple vial strengths that are submitted as individual claims will be subject to recoupment by DMA Program Integrity. Physicians and pharmacy providers are subject to audits of Synagis records by DMA Program Integrity.

Pharmacy Distributor Information

The Synagis for RSV Prophylaxis form must be maintained at the pharmacy distributor's location. The pharmacy distributor must mail a copy of the submitted forms weekly to DMA. Please mail submitted forms to:

NC Division of Medical Assistance
Pharmacy Program
1985 Umstead Drive
2501 Mail Service Center
Raleigh, N.C. 27699-2501

Pharmacy distributors who do a large volume of Synagis claims are asked to submit scanned copies of the Synagis for RSV Prophylaxis form on a compact disk to DMA weekly.
A copy of the approval letter must be maintained at the pharmacy distributor's location if the approval was obtained using the Request for Medical Review for Synagis Outside of Criteria form. The deadline for all pharmacies to submit copies of the Synagis for RSV Prophylaxis form to DMA is April 30, 2008.

Please call Charlene Sampson at (919) 855-4300 if you have questions.

President Signs Bill Delaying Tamper-Resistant Prescription Pad Requirement

On Saturday, September 29, 2007, President George W. Bush signed the Extenders Law, delaying the implementation date for all paper Medicaid prescriptions to be written on tamper-resistant paper. Under the new law, all written Medicaid prescriptions must be on tamper-resistant prescription pads as of April 1, 2008. The previously issued DMA guidance will become effective as of April 1, 2008. This guidance document can be found on the DMA Web site at http://www.dhhs.state.nc.us/dma/TamperResistantPrescriptionPads.pdf. If the Centers for Medicare and Medicaid Services (CMS) offer additional guidance, this document will be updated to reflect any relevant changes.

Verification of Prescriptions On Non-Compliant Tamper Resistant Prescription Pads

In the event that a pharmacist is presented with a non-compliant prescription or questions if a prescription meets the tamper resistant guidelines beginning on April 1, 2008 and elects to call the prescriber to verify it, the prescription must be notated with the following information:

a) initials of the pharmacy staff verifying the prescription
b) date prescription was verified
c) name of the individual (representing the prescriber) who verbally verified the prescription (first and last name)

Prescriptions received electronically or by fax must show that they were received from these telecommunication methods. For example, faxed documents typically display information printed by the fax machine such as the date and time sent as well as the fax number from where the documents originated.

NPI Data Dissemination Now Available

On September 4, 2007, the Centers for Medicare & Medicaid Services (CMS) made available access to the National Plan and Provider Enumeration System (NPPES). The data that is available includes only that health care provider data disclosable under the Freedom of Information Act (FOIA). In accordance with the e-FOIA Amendments, CMS is disclosing this data via the Internet. Data is available in two forms:

1. A query-only database, known as the NPI Registry. The NPI registry operates in a real-time environment and can be found here: https://nppes.cms.hhs.gov/NPPES/NPIRegistryHome.do. UserIDs and passwords are not needed to use the NPI Registry. There is no charge to use the NPI Registry.

2. A downloadable file which will be replaced and updated each month. It can be found here: https://nppesdata.cms.hhs.gov/cms_NPI_files.html. CMS is recommending that providers view their NPI information on the NPI registry to ensure its validity.

If information regarding your NPI is incorrect, please update your information immediately. Providers can log into the NPPES Web site at https://nppes.cms.hhs.gov to make corrections. For questions regarding updates, contact the NPI enumerator by email at customerservice@npienumerator.com or by phone at 1-800-465-3203.

In addition to using this database to validate your information, we recommend that you search this database in the event you need the NPI of a referring provider and the information is not otherwise available. For more information, refer to the data dissemination instructions at: http://www.cms.hhs.gov/NationalProvIdentStand/06a_DataDissemination.asp.

Accepting a Medicaid Recipient

According to 10A NCAC 22J.0106 a provider has a choice whether or not to accept or refuse a patient as a Medicaid patient. However, providers may not discriminate against Medicaid recipients based on the recipient's race, religion, national origin, color, or handicap.
Providers are reminded of the following:

- Medicaid providers must be consistent with their policy and procedures when accepting or refusing Medicaid recipients.
- Acceptance of the recipient's Medicaid ID card and/or submission of a claim for payment to the Medicaid program constitute agreement to accept the Medicaid payment (in addition to any authorized co-payment or third party payment) as payment in full.
- Recipients may not be billed for the difference between the charges and the Medicaid payment in addition to co-payment and third-party payment.
- Recipients may not be billed for any service covered by the Medicaid program unless the provider has specifically informed the recipient that Medicaid will not be billed, and the recipient understands and agrees to accept liability for payment. Providers are encouraged to obtain a signed statement from the patient agreeing to be financially responsible for these charges.
- Recipients must be informed of, and agree to liability for non-covered services *before* such services are rendered.

- Recipients may not be billed for covered services for which the provider is denied payment because the provider failed to follow program regulations. This includes errors on the claim form, late submission, lack of prior approval, failure to bill third-party resources, etc.

A provider may bill a Medicaid recipient if the recipient, rather than the provider, receives payments from either the commercial insurance or Medicare; if the recipient fails to provide proof of eligibility by presenting a current Medicaid card; if the recipient loses eligibility for Medicaid as defined in 10A NCAC 21B; or if the recipient owes an allowable Medicaid deductible or copayment. The following services may also be billed to the recipient:

- Services not covered by Medicaid if the recipient has MEDICARE-AID coverage (MQB-Q; buff colored card)
- Prescriptions in excess of the 11-per month limit, unless the recipient is locked into their pharmacy of record
- Visits in excess of the 30 ambulatory visit limit for the state fiscal year (July 1 through June 30)
- The portion of psychiatric services for a Medicare-eligible recipient that is subject to the 37.5% psychiatric reduction in Medicare reimbursement

For recipients under the age of 21 and EPSDT requirements, see Section 2 and 6 of the Basic Medicaid Billing Guide, available at www.ncdhhs.gov/dma/medbillcaguide.htm.
Providers are encouraged to make use of the resources available to assist in filing claims

- General and special bulletins (www.ncdhhs.gov/dma/cptclickbulletin.htm)
- Clinical coverage policies containing billing information (www.ncdhhs.gov/dma/mp/mpindex.htm)
- Provider Relations staff at EDS, 1-800-688-6696
- Division of Medical Assistance staff
- EDS voice response system for eligibility verification, 1-800-723-4337

Pharmacy Audits

Pursuant to federal regulations regarding utilization of Medicaid services, the Division of Medical Assistance is authorized by Section 1902 (a)(27) of the Social Security Act and Federal Regulation 42 CFR 431.107 to access patient prescriptions for purposes directly related to the administration of the Medicaid program. Therefore, no special recipient permission is necessary for releasing this information. In addition, when applying for Medicaid benefits, each recipient signs a release, which authorizes access to his/her Medicaid records by the appropriate authorities.

Article 5 under Part B of the Medicaid provider agreement states: "That Federal and/or State officials and their contractual agents may make certification and compliance surveys, inspections, medical and professional reviews, and audit of costs and data relating to service to Medicaid patients as may be necessary under Federal and State statutes, rules and regulations. Such visits must be allowed at any time during hours of operation, including unannounced visits. All such surveys, inspections, reviews and audits will be in keeping with both legal and ethical practice governing patient confidentiality."

Article 10 under Part B further states: "That DMA may terminate this agreement upon giving prior written notice or refuse to enter into an agreement when the provider fails to meet conditions for participation, including failure to meet the terms and conditions stated in the provider agreement."

Article 5 under Part A states that the Provider must maintain for a period of five (5) years from the date of service (a) accounting records in accordance with generally accepted accounting principles and Medicaid recordkeeping requirements; and (b) other records as necessary to disclose and document fully the nature and extent of services provided and billed to the Medicaid Program. Such records are subject to audit and review by Federal and State representatives.

Our audits, investigations and inspections are health oversight activities and are subject to the oversight Fraud and Abuse exemption of HIPAA. These disclosures are required by law, and are not subject to minimum necessary (164.502(b) (2) (v). Any disclosures beyond that clearly allowed are considered incidental exposures and are permitted under 164.502(a) (1) (iii). 45 CFR 164.506(a) and 45 CFR 164.512 (k) support our request for private health information.

Impeding or refusing an NC Medicaid audit may result in DMA implementing sanctions, including but not limited to, permanent or temporary termination of the contract and/or recoupments.

False Claims Act Education

Effective January 1, 2007, Section 6023 of the Deficit Reduction Act (DRA) of 2005 requires providers receiving annual Medicaid payments of $5 million or more to educate employees, contractors, and agents about Federal and State fraud and false claims laws and the whistleblower protections available under those laws.

Beginning September 2007 and annually thereafter, the North Carolina Division of Medical Assistance (DMA) will notify providers that they received a minimum of $5 million dollars in NC Medicaid payments during the last federal fiscal year and that they must submit a Letter of Attestation to show that they are in compliance with the DRA. This minimum amount may have been paid to one NC Medicaid provider number or to multiple provider numbers associated with the same tax identification number. Each NC Medicaid provider who receives a notification letter must download a copy of the Letter of Attestation from the DMA Web site and print, sign, and mail it to EDS within 30 days of the date of notification. Downloadable Letter of Attestation forms and a complete list of NC Medicaid provider numbers identified as having received the minimum amount of NC Medicaid payments can be found on our Web site at http://www.ncdhhs.gov/dma/fca/falseclaimsact.html.

Compliance with Section 6023 of the DRA is a condition of receiving Medicaid payments. Medicaid payments will be denied for providers that do not submit a signed Letter of Attestation within 30 days of the date of notification. Providers may resubmit claims once the signed Letter of Attestation is received.

Beginning November 1, 2007, provider enrollment application packets submitted to DMA must include the signed Letter of Attestation. An enrollment application packet is considered received by DMA when it is current, complete, original, and signed.

Changes in Drug Rebate Manufacturers

The following changes are being made in manufacturers with Drug Rebate Agreements. They are listed by manufacturer code, which are the first five digits of the NDC.

Voluntarily Terminated Labelers

The following labelers have requested voluntary termination effective October 1, 2007:

Delta Pharmaceuticals, Inc.	(Labeler 53706)
F. Dohman (AKA HEALTHCARE AMERICA ([HCA])	(Labeler 64899)
Santen Incorporated	(Labeler 65086)
Axiom Pharmaceutical Corporation	(Labeler 67870)

Checkwrite Schedule

October 09, 2007	November 06, 2007	December 04, 2007
October 16, 2007	November 14, 2007	December 11, 2007
October 23, 2007	November 21, 2007	December 20, 2007
October 31, 2007		

Electronic Cut-Off Schedule

October 04, 2007	November 01, 2007	December 06, 2007
October 11, 2007	November 08, 2007	December 13, 2007
October 18, 2007	November 15, 2007	
October 25, 2007	November 29, 2007	

Electronic claims must be transmitted and completed by 5:00 p.m. on the cut-off date to be included in the next checkwrite. Any claims transmitted after 5:00 p.m. will be processed on the second checkwrite following the transmission date. POS claims must be transmitted and completed by 12:00 midnight on the day prior to the electronic cut-off date to be included in the next checkwrite.

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